AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application

1. (currently amended) A multi-particulate pharmaceutical dosage form of a skeletal muscle relaxant providing a modified release profile comprising a population of extended release beads,

wherein said extended release beads comprise

an active-containing core particle comprising a skeletal muscle relaxant selected from the group consisting of cyclobenzaprine, pharmaceutically acceptable salts or derivatives thereof and mixtures thereof; and

an extended release coating comprising a water insoluble polymer membrane surrounding said core,

wherein said dosage form when dissolution tested using United States Pharmacopoeia Apparatus 2 (paddles @ 50 rpm) in 900 mL of 0.1N HCl at 37°C exhibits a drug release profile substantially corresponding to the following pattern:

after 2 hours, no more than about 40% of the total active is released;

after 4 hours, from about 40-65% of the total active is released

after 8 hours, from about 60-85% of the total active is released;

wherein said dosage form provides therapeutically effective plasma concentration over a period of 24 hours to treat muscle spasm associated with painful musculoskeletal conditions when administered to a patient in need thereof; and

wherein said water insoluble polymer membrane comprises a water insoluble polymer selected from the group consisting of ethers of cellulose, esters of cellulose, cellulose acetate, cellulose butyrates, cellulose propionate, ethyl cellulose, mixed cellulose esters, acylated polysaccharides, polyurethanes, polyacrylate and polymethacrylate polymers and derivatives, waxes, polyvinyl acetate, neutral copolymers based on ethylacrylate and methylmethacrylate, copolymers of acrylic and methacrylic acid esters with quaternary ammonium groups, pH-insensitive ammonio methacrylic acid copolymers, and mixtures thereof.

2. (currently amended) ~~A~~ The pharmaceutical dosage form ~~as defined in~~ of claim 1,

wherein said skeletal muscle relaxant comprises cyclobenzaprine hydrochloride.

3. (currently amended) ~~A~~ The pharmaceutical dosage form ~~as defined in~~of claim 2 wherein said pharmaceutical dosage form provides a maximum blood plasma concentration (C_{max}) within the range of about 80% to 125% of about 20 ng/mL of cyclobenzaprine HCl and an AUC_{0-168} within the range of about 80% to 125% of about 740 ng·hr/mL and a T_{max} within the range of 80% to 125% of about 7 hours following oral administration of a single 30 mg cyclobenzaprine HCl MR Capsule.

4. (currently amended) ~~A~~ The pharmaceutical dosage form ~~as defined in~~of claim 3 wherein the adjusted mean ratio of CMR 30 mg/CMR 15 mg is greater than about 2 for each of AUC_{0-168} ($p<0.001$), $AUC_{0-\infty}$ ($p<0.001$), and C_{max} ($p<0.001$).

5. (currently amended) ~~A~~ The pharmaceutical dosage form ~~as defined in~~of claim 1 further comprising an immediate release bead population, wherein said immediate release beads comprise an active-containing core particle comprising cyclobenzaprine, pharmaceutically acceptable salts or derivatives thereof and mixtures thereof~~a skeletal muscle relaxant~~ and said immediate release beads when tested in a USP Type 2 Apparatus at 50 rpm in 900 ml 0.1 N HCl at 37°C release at least about 70% of the cyclobenzaprine, pharmaceutically acceptable salts or derivatives thereof and mixtures thereof ~~active~~ within 30 minutes.

6. (currently amended) ~~A~~ The pharmaceutical dosage form ~~as defined in~~of claim 1, wherein said dosage form comprises only one extended release bead population.

7. (currently amended) ~~A~~ The pharmaceutical dosage form ~~as defined in~~of claim 1, wherein said water insoluble polymer membrane comprises a water insoluble polymer ~~is~~ selected from the group consisting of ethers of cellulose, ~~and~~ esters of cellulose, ethyl cellulose, cellulose acetate, polyvinyl acetate, neutral copolymers based on ethyl acrylate and methylmethacrylate, copolymers of acrylic and methacrylic esters with quaternary ammonium groups, pH-insensitive ammonio methacrylic acid copolymers, and mixtures

thereof.

8. (currently amended) ~~A~~ The pharmaceutical dosage form ~~as defined in~~ of claim 7, wherein said extended release coating further comprises a plasticizer.

9. (currently amended) ~~A~~ The pharmaceutical dosage form ~~as defined in~~ of claim 8, wherein said plasticizer is selected from the group of triacetin, tributyl citrate, tri-ethyl citrate, acetyl tri-n-butyl citrate, diethyl phthalate, dibutyl sebacate, polyethylene glycol, polypropylene glycol, castor oil, acetylated mono- and di-glycerides and mixtures thereof.

10. (currently amended) ~~A~~ The pharmaceutical dosage form ~~as defined in~~ of claim 1, wherein said water insoluble polymer membrane on the drug cores comprises from about 7% to 12% by weight of the ~~coated~~ extended release beads.

11. (currently amended) ~~A~~ The pharmaceutical dosage form ~~as defined in~~ of claim 7, wherein said extended release coating further comprises a water soluble polymer selected from the group consisting of methylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, polyethylene glycol polyvinylpyrrolidone and mixtures thereof.

12-23. (canceled)

24. (currently amended) ~~A~~ The pharmaceutical dosage form ~~as defined in~~ of claim 1, wherein said skeletal muscle relaxant comprises cyclobenzaprine.

25. (new) The pharmaceutical dosage form of claim 1, wherein said drug release profile substantially corresponds to the following pattern:

after 2 hours, no more than about 40% of the total active is released;

after 4 hours, from about 40-65% of the total active is released;

after 8 hours, from about 60-85% of the total active is released; and

after 12 hours, from about 75- 85% of the total active is released.

26. (new) The pharmaceutical dosage form of claim 9, wherein said extended release coating further comprises a water soluble polymer selected from the group consisting of methylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, polyethylene glycol polyvinylpyrrolidone and mixtures thereof.

27. (new) The pharmaceutical dosage form of claim 7, wherein the water insoluble polymer membrane comprises ethyl cellulose.

28. (new) The pharmaceutical dosage form of claim 27, wherein said extended release coating further comprises a plasticizer.

29. (new) The pharmaceutical dosage form of claim 28, wherein said plasticizer is diethyl phthalate.

30. (new) The pharmaceutical dosage form of claim 28, wherein the extended release coating further comprises a water soluble polymer selected from the group consisting of methylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, polyethylene glycol polyvinylpyrrolidone and mixtures thereof.

31. (new) The pharmaceutical dosage form of claim 29, wherein the extended release coating further comprises a water soluble polymer selected from the group consisting of methylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, polyethylene glycol polyvinylpyrrolidone and mixtures thereof.

32. (new) The pharmaceutical dosage form of claim 31, wherein the water soluble polymer is hydroxypropyl methylcellulose.

33. (new) The pharmaceutical dosage form of claim 32, wherein the skeletal muscle relaxant is cyclobenzaprine hydrochloride.

34. (new) The pharmaceutical dosage form of claim 33, wherein the water insoluble

polymer membrane comprises from about 7% to 12% by weight of the extended release beads.

35. (new) The pharmaceutical dosage form of claim 34, wherein the drug release profile substantially corresponds to the following pattern:

after 2 hours, no more than about 40% of the total active is released;

after 4 hours, from about 40-65% of the total active is released;

after 8 hours, from about 60-85% of the total active is released; and

after 12 hours, from about 75- 85% of the total active is released.

36. (new) The pharmaceutical dosage form of claim 1, wherein said water insoluble polymer membrane comprises a water insoluble polymer selected from the group consisting of ethers of cellulose, esters of cellulose, pH-insensitive ammonio methacrylic acid copolymers, and mixtures thereof.

37. (new) The pharmaceutical dosage form of claim 36, wherein said extended release coating further comprises a plasticizer.

38. (new) The pharmaceutical dosage form of claim 37, wherein the plasticizer is selected from the group of triacetin, tributyl citrate, tri-ethyl citrate, acetyl tri-n-butyl citrate, diethyl phthalate, dibutyl sebacate, polyethylene glycol, polypropylene glycol, castor oil, acetylated mono- and di-glycerides and mixtures thereof.

39. (new) The pharmaceutical dosage form of claim 36, wherein said extended release coating further comprises a water soluble polymer selected from the group consisting of methylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, polyethylene glycol polyvinylpyrrolidone and mixtures thereof.

40. (new) The pharmaceutical dosage form of claim 37, wherein said extended release coating further comprises a water soluble polymer selected from the group consisting of methylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, polyethylene

glycol polyvinylpyrrolidone and mixtures thereof.